

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

NOVARTIS PHARMACEUTICALS CORPORATION,
NOVARTIS CORPORATION, NOVARTIS AG, and
NOVARTIS PHARMA AG,

Plaintiffs,

v. // CIVIL ACTION NO. 1:14CV111
(Judge Keeley)

MYLAN INC. and MYLAN PHARMACEUTICALS,
INC.,

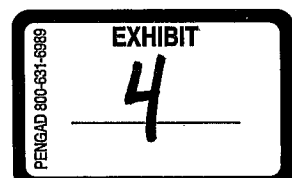
Defendants.

ORDER GRANTING PLAINTIFFS' RENEWED MOTION TO STAY
[DKT. NO. 63] AND DENYING AS MOOT DEFENDANT'S
MOTION FOR CLARIFICATION [DKT. NO. 65]
AND MOTION TO COMPEL [DKT. NO. 66]

On June 26, 2014, the plaintiffs, Novartis Pharmaceuticals Corporation, Novartis Corporation, Novartis AG, and Novartis Pharma AG (collectively, "Novartis"), filed a complaint for patent infringement against defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively, "Mylan") (Dkt. No. 1).¹ Mylan filed its answer and counterclaim on December 4, 2014 (Dkt. No. 31), and Novartis filed its answer to the counterclaim on December 23, 2014 (Dkt. No. 36).

On November 24, 2014, Novartis filed its first motion to stay this case as a second-filed suit pending resolution of a jurisdictional dispute in the first-filed suit in the United States

¹ The day before, on June 25, 2014, Novartis had filed an identical complaint in the United States District Court for the District of Delaware, making the suit in this district a second-filed action (Dkt. No. 30 at 6, Dkt. No. 30-3).



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District Court for the District of Delaware (Dkt. No. 29). The Court denied Novartis' motion on January 29, 2015, finding that the serious jurisdictional dispute and lack of progress in the first-filed case mitigated against granting a stay at that time (Dkt. No. 38 at 12-16).

On March 26, 2015, Novartis renewed its motion to stay the instant case, arguing that the jurisdictional dispute in the District of Delaware had been resolved, and that the first-filed case was moving forward (Dkt. No. 63). On April 9, 2015, Mylan responded, arguing that the personal jurisdiction will remain contested in the District of Delaware until the United States Court of Appeals for the Federal Circuit resolves issues of personal jurisdiction similar to those in dispute in the first-filed case (Dkt. No. 72). On April 16, 2015, Novartis filed a reply (Dkt. No. 74). The motion is now fully briefed and ripe for disposition.

I. Background

Novartis holds two patents² and a new drug application ("NDA") for EXJADE, a drug "indicated for the treatment of chronically

² Patent No. 6,465,504 ("the '504 Patent"), issued on October 15, 2002, and Patent No. 6,596,750 ("the '750 Patent"), issued on July 22, 2003, cover EXJADE (Dkt. No. 1 at 1, 6-7).

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elevated levels of iron in the blood caused by repeated blood transfusions."³ (Dkt. No. 1 at 6-7). EXJADE is a tablet for oral suspension with the active ingredient deferasirox. U.S. Food and Drug Administration, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, available at <http://www.accessdata.fda.gov/scripts/cder/ob/docs/temptn.cfm> (last updated Apr. 24, 2015).

On May 13, 2014, Mylan notified Novartis that it had filed an abbreviated new drug application ("ANDA") containing a Paragraph IV certification that Novartis' patents for EXJADE are invalid, unenforceable, or will not be infringed by its ANDA. On June 26, 2014, Novartis filed its complaint alleging patent infringement, and seeking various forms of relief, including: 1) a judgment that Mylan infringed its patents; 2) a judgment that the patents are valid and enforceable; 3) an order stating that the effective date of any FDA approval of Mylan's ANDA should be after Novartis' patents expire; 4) an injunction restraining Mylan from

³ For a description of EXJADE and its indications, see http://www.us.exjade.com/index.jsp?usertrack.filter_applied=true&NovaId=2935376999746121108 (last visited Apr. 27, 2015).

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manufacturing, using, offering to sell, or selling a generic version of EXJADE; 5) damages; and, 6) costs and reasonable attorneys' fees (Dkt. No. 1 at 10-11).

On December 4, 2014, Mylan filed an answer and counterclaim, denying any infringement of Novartis' patents, and countering that the patents are invalid (Dkt. No. 31 at 17-26). Mylan seeks a declaration that its manufacture, use, offer for sale, importation, or sale of its generic version of EXJADE does not infringe Novartis' patents, a declaration that the patents are invalid, dismissal of Novartis' complaint with prejudice, as well as attorneys' fees and costs. Id. at 26-27.

When Novartis filed its original motion to stay the instant case on November 24, 2014, it argued the Court should stay the case until the District of Delaware resolved a pending jurisdictional dispute in the first-filed case (Dkt. No. 30 at 5). Prior to that, on August 6, 2014, Mylan had filed a motion in Delaware seeking to dismiss the first-filed case based on lack of jurisdiction (Dkt. No. 34-1). On March 16, 2015, Judge Andrews of the District of Delaware denied Mylan's motion to dismiss, finding that Mylan Pharmaceuticals Inc. was subject to general jurisdiction under the

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Delaware long-arm statute (Dkt. No. 63 at 2).⁴ Therefore, Novartis contends, jurisdiction in the District of Delaware is no longer in dispute, and this Court should stay the instant suit under the first-to-file rule.

In its response, Mylan argues that the jurisdictional dispute in Delaware is "far from over," because the Federal Circuit granted Mylan's petitions for interlocutory appeal regarding similar personal jurisdiction issues (Dkt. No. 72 at 5).⁵ See, e.g., Acorda Therapeutics, Inc. v. Mylan Pharm. Inc., No. 2015-124 (Fed. Cir. Mar. 17, 2015); AstraZeneca AB v. Mylan Pharm. Inc., No. 2015-117 (Fed. Cir. Mar. 17, 2015). The Federal Circuit's decisions in Acorda and AstraZeneca "will be dispositive of the personal jurisdiction issue in the Delaware Action." (Dkt. No. 72 at 5). On March 31, Mylan filed a motion to stay the first-filed case pending before Judge Andrews. Id. at 6, 8.

⁴ Judge Andrews granted jurisdictional discovery as to Mylan Inc. (Dkt. No. 63 at 2, n. 3). The parties later stipulated to the dismissal of Mylan Inc. from the Delaware case (Dkt. No. 74 at 6, n. 2).

⁵ Mylan indicated that it does not intend to seek interlocutory appeal of Judge Andrews' decision in the first-filed case (Dkt. No. 72 at 8).

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II. Applicable Law

The first-to-file rule is an equitable doctrine that "favors the forum of the first-filed action" Genentech, Inc. v. Eli Lilly and Co., 998 F.2d 931, 937 (Fed. Cir. 1993), abrogated on other grounds, Wilton v. Seven Falls Co., 515 U.S. 277, 115 S.Ct. 2137 (1995). The primary policies underlying the first-to-file rule are the avoidance of duplicative litigation, the promotion of uniformity of results, and the conservation of judicial resources. See Colorado River Water Conservation District v. United States, 424 U.S. 800, 817, 96 S.Ct. 1236 (1976); Cadle Co. v. Whataburger of Alice, Inc., 174 F.3d 599, 604 (5th Cir. 1999).

When two courts have concurrent jurisdiction in substantially identical cases, the court hearing the second-filed action generally defers to the court hearing the first-filed action. See Merial Ltd. v. Cipla Ltd., 681 F.3d 1283, 1299 (Fed. Cir. 2012). Courts usually consider three factors to determine whether the first-to-file rule applies. These include 1) chronology, 2) identity of parties, and 3) similarity of issues. Intersearch Worldwide, Ltd. v. Intersearch Group, Inc., 544 F.Supp.2d 949, 957 (N.D. Cal. 2008).

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Importantly, in first-filed cases where jurisdiction is unsettled, courts have held that the first-to-file rule does not apply. See, e.g., Genentech, 998 F.2d at 938 (listing the absence of jurisdiction as a "sound reason that would make it unjust or inefficient to continue the first-filed action."); Orthmann v. Apple River Campground, Inc., 765 F.2d 119, 121 (8th Cir. 1985) (dismissing the first-filed action, where jurisdiction was "vigorously dispute[d]," to allow the second-filed action to progress).

Some courts, however, have determined that jurisdiction in the first-filed case is just one of several factors to consider. See Cadle Co., 174 F.3d at 605 ("While the likelihood of a jurisdictional dispute in the first-filed court may be a factor to consider in applying the rule, resolving the dispute in favor of that court's jurisdiction is never a condition precedent to applying it."); Brower v. Flint Ink Corp., 865 F.Supp. 564, 570 (N.D. Iowa 1994) (noting that jurisdictional considerations are one of many factors when determining what circumstances are compelling enough to overcome the first-to-file rule).

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The first-to-file rule is subject to various exceptions, including consideration of whether the balance of convenience weighs in favor of the second-filed court's continued exercise of jurisdiction over the suit, whether the suit is filed in bad faith, or whether the suit is filed for the purposes of forum shopping. EEOC v. Univ. of Pa., 850 F.2d 969, 976 (3d Cir. 1988); Ellicott Mach. Corp. v. Modern Welding Co., 502 F.2d 178, 181 (4th Cir. 1974). It is the province of the first-filed court, however, to determine "whether an exception to the first-filed rule applies." Touchstone Research Lab, Ltd. v. Anchor Equip. Sales, Inc., 294 F.Supp.2d 823, 828 (N.D.W. Va. 2003) (quoting Citigroup Inc v. City Holding Co., 97 F.Supp.2d 549, 557 n.4 (S.D.N.Y. 2000)).

III. Legal Analysis

In its previous Order Denying the Plaintiffs' Motion to Stay, the Court declined to apply the first-to-file rule based on a serious jurisdictional dispute and lack of progress in the first-filed case (Dkt. No. 38 at 10-12). Now, the landscape of the first-filed case has changed significantly, such that the Court finds it appropriate to revisit its earlier ruling. See id. at 15

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(inviting Novartis to renew its motion to stay "should the District of Delaware resolve the jurisdictional dispute in its favor.").

In the Court's January 29, 2015, Order, it found significance in the fact that Mylan could be "faced with the possibility of both a stay in this case and a long wait in the District of Delaware should that court choose to withhold its decision on Mylan's motion to dismiss until the Federal Circuit decides the interlocutory appeal in AstraZeneca." (Dkt. No. 38 at 14). Now, Judge Andrews has not only denied Mylan's motion to dismiss, but also has scheduled the case for trial (Dkt. No. 74-1; Dkt. No. 74 at 7). Unlike the earlier situation, where the parties would potentially face a lengthy delay in proceedings, the first-filed suit is proceeding at a rapid pace under Judge Andrews' direction. See Dkt. No. 74 at 7 ("The scheduling orders in both districts reflect the same dates for the close of fact and expert discovery . . . [and] the trial [in the instant case] is actually scheduled five months later than the trial would occur in Delaware."). Judge Andrews is already addressing a discovery dispute dealing with the production of prior litigation documents, leading this Court to

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deny Mylan's motion to expedite a similar ruling here "to avoid duplication and inefficiency." (Dkt. No. 71 at 2).

Importantly, the considerations underlying the first-to-file rule require that this Court grant Novartis' motion to stay. The first-to-file rule "is a doctrine of federal comity, intended to avoid conflicting decisions and promote judicial efficiency." Merial, 681 F.3d at 1299. It would hardly promote efficiency or uniformity to proceed with a second case in this district when the first-filed case is already proceeding in the District of Delaware. The Court therefore declines to adopt Mylan's proposal to deny Novartis' motion to stay until the Federal Circuit rules on its interlocutory appeal. It agrees with Novartis that any other ruling "would imply that district courts should defer only to appellate decisions, thereby vitiating the first-to-file rule and rejecting its central premise-deference to the first-filed jurisdiction under the principle of comity." (Dkt. No. 74 at 7).

Should the United States Court of Appeals for the Federal Circuit later conclude that Mylan is not subject to personal jurisdiction in the District of Delaware, the case can easily be

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transferred to this district. Thus, granting the motion to stay does not leave Mylan without a remedy.

For all of the reasons discussed, the Court **GRANTS** Novartis' renewed motion to stay (Dkt. No. 63), and **DENIES AS MOOT** Mylan's motion for clarification (Dkt. No. 65), and motion to compel (Dkt. No. 66). Finally, it **ORDERS** the parties to inform the Court on a timely basis of any developments regarding the outcome of Mylan's interlocutory appeal or otherwise affecting its jurisdictional status in the District of Delaware.

It is so **ORDERED**.

The Court directs the Clerk to transmit copies of this Order to counsel of record.

DATED: April 27, 2015.

/s/ Irene M. Keeley
IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE